

REMARKS

Claims 1, 4, 5, 8-16, 18-43, 45-70, 76, 77, 81-86, 88, and 90-108 are now pending in the application. Claims 2, 3, 17, 78-80, 87, and 89 are canceled and claim 105 - 108 are added by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

New Claims 105 - 108 are within the scope of the previously made election.

SUMMARY OF APPLICANT INITIATED INTERVIEW WITH EXAMINER

Applicants would like to thank the Examiner for the interview granted January 16, 2009. The Examiner, however, only allowed a brief interview due to a prior interview. During the interview of January 16, 2009 only Independent Claim 1 and a guide tube, as recited in Independent Claim 68, was discussed. Many of the claims in the current application were not previously rejected or were objected to claims placed into independent format and only now rejected based on newly cited art. Accordingly, Applicants requests a full interview to discuss all pending claims if all of the claims are not found to be in condition for allowance.

During the brief interview, Applicants' representative submitted that the art did not teach a fiducial marker with a locatable portion. Although an agreement was not reached that such claims would be allowable, Applicants' representative believes an agreement was reached that the Examiner will contact Applicants' representative if the Examiner believes additional language or clarification is needed to identify a single-piece or unitary member.

APPLICANT INITIATED INTERVIEW REQUEST

The present Office Action rejects all of the pending claims, many of which were amended into independent format based upon the indication of objected to but allowable claims in the Office Action mailed February 6, 2008. In the February Office Action, Claims 10, 11, 22, 25, 26, 36, 49, 52, 53, 64, 65, 68, 76, 81, 88, 94, and 98, and 101 were all indicated as allowed or allowable. Applicants amended these claims into independent format and into condition for allowance. The current Office Action, however, includes newly cited art to reject these claims for a **first** time. Applicants, therefore, respectfully request an interview with the Examiner if all of these claims are not found to be in condition for allowance in light of the previous indication of allowability.

REJECTION UNDER 35 U.S.C. § 103

All of the claims as pending prior to this amendment stand rejected under 35 U.S.C. 103(a) as being unpatentable in light of a combination of cited art. All of the outstanding rejections are respectfully traversed. Applicants submit that the amendments and arguments presented herein render moot the outstanding rejections and that all of the pending claims are not anticipated or fairly rendered obvious by any of the cited art, alone or in combination. Applicants, therefore, respectfully request that the Examiner withdraw all of the rejections.

Each of the independent claims is discussed in detail below under separate headings. Although all of the dependent claims are not discussed in detail, Applicants

submit that all of the dependent claims are in condition for allowance at least because the claim from which each depends is in condition for allowance.

Reasons for a Combination and Improper Hindsight Reasoning

A combination of cited art to reject a Claim must be made based on a claim as a whole. "Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language . . . and considering both the invention and the prior art as a whole." See, MPEP § 2141 (II)(B). Accordingly, finding a single element or phrase in a reference is not proper if there is no reason or operable solution for the combination.

When a rejection is based on a combination of cited art, the combination must be based upon a sound reason provided by the Office. "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396." See, MPEPE 2141 (III). In addition, the reason must not be based upon hindsight reasoning. If no real and sound reason is provided by the Office, then the combination of cited art and the rejection based on the submitted combination is improper. See, MPEPE 2141 (III).

Applicants submit that the proposed "reason" that one skilled in the art **could** do something is not a sound reason; it is, at best, a conclusion. Simply because one skilled in the art could find each of the claimed elements in several references does not provide the sound reason or know-how to do so. Such an unsound reason could only be reached using improper hindsight reasoning.

Improper hindsight reasoning uses the present claim as a roadmap to combine the teachings of the prior art. In essence, improper hindsight reasoning gives one skilled in the art **NOW** (i.e., after reading the present application and claims) perfect vision looking backwards when researching the art. Applicants submit that the reason for the combination **must** be present in the art at the time of the invention, i.e. the **PAST**. Accordingly, one skilled in the art **NOW**, i.e. after reading the current applicant and claims, is **not** one of ordinary skill in the art at the time of the invention and can not be used when examining the current claims.

Applicants submit that simply finding various elements of the claims in the art is not enough to reject the pending claims. A reason for a combination of cited art must be based on the art, the skill of one in the art to solve a known problem in the art, etc. In addition, the reason must be clearly stated in a rejection for the rejection to be proper.

Accordingly, when no proper reason is given in the current Office Action for a rejection based on a combination of cited art, the rejection is not proper and must be withdrawn. Particularly rejections based on combinations of non-analogous art, such as a fiducial and a non-analogous bone stimulation system, should be withdrawn.

Independent Claim 1

Independent Claim 1 stands rejected based on three combinations, (1) the combination of Leibinger et al. (U.S. Pat. No. 5,394,457 (herein Leibinger) and Vilsmeier (U.S. Pat. No. 6,351,659); (2) Allen (U.S. Pat. No. 5,397,329) and Vilsmeier; and (3) Franklin et al. (U.S. Pat. No. 6,327,491 (herein Franklin)) and Vilsmeier.

Leibinger discloses a fixture, such as a fixture 10, into which a marker 18, including a limb 22 and a head 24, is placed. The head 24 can be imaged with appropriate imaging systems once it is interconnected with a fixture. Vilsmeier discloses **two separate prominences**, a first landmark prominence 70, that is imaged, and a second landmark prominence 80, having a funnel 83, are **separately and sequentially** connected with a fastener 90. Franklin discloses that a bone anchor 120 is connected with a scanning marker 122. Finally, Allen discloses that a fiducial implant 10 is connected to a patient. Allen further discloses that a tip of a robot arm includes a sensor, such as a metal detector or ultrasonic detector, to sense a position of the fiducial implant 10. All of Leibinger, Vilsmeier, Franklin, and Allen disclose a member that can be imaged in an imaging device for image data. Only Vilsmeier discloses a member that can be contacted at a center to identify a center of the member. Vilsmeier, however, requires that the second landmark prominence 80 be connected with the fastener 90 after the first imageable prominence 70 is removed from the fastener to identify the location. See, Vilsmeier, Col. 13, Line 1 – Col. 14, Line 36. As discussed with the Examiner, therefore, none of the cited art, either alone or in combination, anticipate or fairly render obvious a one-piece fiducial marker or member as recited in

Independent Claim 1. The fiducial marker or member of Independent Claim 1 includes a single-piece fiducial marker . . . an imageable fiducial locator head . . . a conical receptacle defined by the imageable fiducial locator head . . . and a bone-screw shaft extending directly outward from the imageable fiducial locator head.

As noted above, Applicants submit that a real and concrete reason for a combination must also be provided to support a combination of cited art. The Office, however, simply states that references, such as Leibinger and Vilsmeier could be combined to make a single-piece fiducial marker. The Office fails to reason how or why this would be done in light of the disclosure of a two piece system described in both references. In addition, Applicants submit that there is no real reason to combine Franklin and Vilsmeier. Though the Office notes that one skilled may wish to increase precision, Applicants submit that the combined art does not disclose how increased precision would be achieved or how the increased precision would render obvious the present claims.

Further, Applicants respectfully submit that Vilsmeier actually teaches away from Independent Claim 1 because Vilsmeier discloses two prominences and not a single-piece fiducial marker. Applicants respectfully submit that Independent Claim 1, in addition to being structurally distinct from the cited art, allows locating the imageable fiducial locator head with an imaging system and with an instrument via a conical receptacle, as recited in Independent Claim 1. Even assuming that Vilsmeier includes an imageable fiducial locator and a conical receptacle, as recited in Independent Claim 1, Vilsmeier requires that **two prominences** be separately and sequentially connected with the fastener to allow imaging and instrument location of a point.

The cited art also fails to anticipate or fairly render obvious a bone screw shaft as recited in Independent Claim 1. All of Vilsmeier, Franklin, and Leibinger only disclose that an imageable portion is positioned with a **separate** member and not as one-piece. While Allen discloses that the fiducial implant 10 can include a first portion 12 and second portion 14 that is configured to be fixed to bone, Allen fails to disclose a fiducial mark or member that includes an imageable fiducial locator head and a conical receptacle defined by the imageable fiducial locator head, as recited in Independent Claim 1.

Claim 31 depends from Independent Claim 1, and is rejected under the combination of Franklin, Vilsmeier, and Franck et al. (U.S. Pat. No. 6,273,896 (herein Franck)). Applicants submit that none of these references, alone or in combination, disclose the imageable locator head that defines a receptacle as recited in Independent Claim 1. Thus, these references can not render obvious Claim 31. In addition, Claim 31 recites, "a headband defining holes sized and shaped for protecting the fiducial marker." The Office cites only Franck for a headband. Applicants note that Franck does not disclose a headband with holes for protecting a fiducial marker or for protecting a fiducial marker in any manner. Franck does disclose "an arc-shaped MIRRF 1410," but this attaches to inserts and does not protect a fiducial marker. See, Franck, col. 16, lns. 49-59. In fact, Franck discloses and illustrates that the fiducial marker 1412 is on an exterior of the MIRRF 1410 and not within a hole of a headband. See, Franck, col. 16, lns. 49-59 and Fig. 20.

Accordingly, Independent Claim 1 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 10

Independent Claim 10 stands rejected based on the combination of Franklin, Vilsmeier, and Overaker et al. (U.S. Pat. No. 6,241,732 (herein Overaker)).

As discussed above, Vilsmeier does not disclose a fiducial marker with a head that defines both an imageable fiducial locator head and a conical receptacle. As discussed above, Vilsmeier requires at least two separate prominences to form an image and locate a position. Similarly, Franklin discloses markers and a fixture that is separately and sequentially connected to the bone anchors. Thus, Franklin does not overcome the failure of Vilsmeier. Finally, Overaker is directed to a resorbable rivet and does not disclose a fiducial of any type. Thus, Applicants submit that the cited art does not anticipate or fairly render obvious at least, "an imageable fiducial locator head . . . a conical receptacle . . . defined within the imageable fiducial locator head, wherein access to a center of the imageable fiducial locator head is permitted with the conical receptacle," as recited in Independent Claim 10.

Further, Overaker does not disclose a hygroscopic material. Applicants submit that Overaker actually discloses a material that only degrades when exposed to a liquid, such as water. Overaker discloses that the disclosed material will degrade mainly through hydrolysis. See, Overaker, col. 7, lns. 28-31. Thus, Overaker can not anticipate, either alone or in combination with the other cited art, that an "imageable fiducial locator head includes a hygroscopic material," as recited in Independent Claim 10.

Accordingly, Independent Claim 10 is in condition for allowance.

Independent Claim 11

Independent Claim 11 is rejected under the combination of Leibinger and Vilsmeier.

Independent Claim 11 recites, "an imageable fiducial locator head . . . a conical receptacle . . . defined within the imageable fiducial locator head, wherein access to a center of the imageable fiducial locator head is permitted with the locator instrument." As discussed above, Applicants submit that the combination of Leibinger and Vilsmeier does not disclose a fiducial marker with an imageable fiducial locator head where the head also defines a conical receptacle within the head, as recited in Independent Claim 11. The cited art requires at least two members to provide for an imageable portion and a portion defining anything that can reasonably be understood to be a receptacle. Further, Applicants submit that a proper reason for combining Leibinger and Vilsmeier has not been provided.

In addition, Independent Claim 11 recites, "a seat in at least one of the imageable fiducial locator head and the shaft, the seat including a kerf operable to accommodate therein loose bone fragments that are channeled upward by the bone screw shaft as it is being secured to the bone." As disclosed in paragraph 99 of the subject application, a "kerf 1306 accommodates therein loose bone fragments that are channeled upward by the threads 1110 when the fiducial marker 1100 is being screwed into the skull." Accordingly, a kerf, as claimed, provides an area that can receive a volume of material. The Office simply states that Leibinger discloses a seat and kerf in Figure 3. See, Office Action, p. 3, last line. The marker 18 of Leibinger, illustrated in Fig. 3, is

disclosed to be pushed into a fixture 10, as illustrated in Figs. 1, 4, and 5. Thus, the marker 18 does not engage a bone and does not include a kerf. Moreover, Applicants submit that no other portions of Leibinger or Vilsmeier disclose a kerf.

Accordingly, Independent Claim 11 is in condition for allowance.

Independent Claim 22

Independent Claim 22 strands rejected under the combinations of (1) Leibinger and Vilsmeier; and (2) Franklin, Vilsmeier, Stednitz et al. (U.S. Pat. No. 5,098,435 (herein Stednitz)), Ferrante et al. (U.S. Pat. No. 6,565,573 (herein Ferrante)), Grafton (U.S. Pub. No. 2001/0051807), and Leclair (U.S. Pat. Pub. No. 2004/0254581).

Independent Claim 22 recites, "an imageable fiducial locator head . . . a conical receptacle . . . defined within the imageable fiducial locator head, wherein access to a center of the imageable fiducial locator head is permitted with the conical receptacle; and a bone screw shaft that extends directly outward from the imageable fiducial locator head." As discussed above, Applicants submit that the combination of Leibinger and Vilsmeier does not anticipate or fairly render obvious a fiducial marker with a locator head that is both imageable and defines a conical receptacle, as recited in Independent Claim 22. In addition, neither Leibinger nor Vilsmeier disclose a shaft that includes "a laterally expandable distal tip." As noted above, Applicants submit that no proper reason for combining Leibinger and Vilsmeier has been provided. Thus, neither Leibinger nor Vilsmeier can anticipate or fairly render obvious Independent Claim 22.

The combination of Franklin and Vilsmeier with either Stednitz or Ferrante, as submitted by the Office, appears to be improper. While the Office submits that Franklin

and Vilsmeier can be combined with Stednitz or Ferrante to render obvious a fiducial marker including a shaft, as presently claimed, this does not appear to be disclosed in the art. In fact, the cited art appears to teach against such a combination. As discussed above, Vilsmeier does not disclose a shaft, but rather includes a fastener 90 that can include a sticky plaster to be attached to a patient, such as the skin of the patient. Two prominences, one imageable and one for location identification can then be sequentially connected with the fastener. Franklin discloses a system where a marker 122 is connected with a bone anchor 120. After scanning, the scanning marker 122 is removed and a fixture is connected with the bone anchor 120. See, Franklin, col. 5; Ins. 1-7. Therefore, neither Vilsmeier nor Franklin disclose a system that allows a fiducial marker to be connected directly to the patient. In Vilsmeier, it would be impossible to replace the imageable portion with the locatable portion if the fastener 90 was not maintained in place and in Franklin the fixture can not be attached to the patient without the bone anchors 120. Accordingly, even assuming that Stednitz and Ferrante disclose a shaft as presently claimed, their combination with either or both of Vilsmeier and Franklin is improper and the art actually teaches away from such a combination.

Leclair and Grafton are cited for disclosing a laterally expandable distal tip. Independent Claim 22 has been amended to recite "a passage is defined by the conical receptacle defined within the imageable fiducial locator head and through the shaft; wherein a member extends through the passage and the member is operable to be manipulated through the conical receptacle to be rotated to expand the expandable distal tip; wherein the imageable fiducial locator head defines threads and the member defines complementary threads." Leclair discloses a furcated bone screw that can pass

through a plate and expand. Leclair does not disclose a member for expanding a tip, as recited in Independent Claim 22. In addition, Leclair does not disclose any portion that can be reasonable understood to be a fiducial marker. Grafton also fails to disclose any portion that can be an imageable fiducial locator head as claimed. Accordingly, Grafton does not disclose a passage through at least a portion of an imageable fiducial locator head, as presently claimed, and does not overcome the failings of Leclair or any of the other cited art to render obvious Independent Claim 22.

Accordingly, Independent Claim 22 is in condition for allowance.

Independent Claim 23

Independent Claim 23 stands rejected under the combinations of (1) Leibinger and Vilsmeier and (2) Franklin, Vilsmeier, and Gordon (U.S. Pat. No. 5,300,075).

Independent Claim 23 has been amended to recite "an imageable fiducial locator head . . . a conical receptacle . . . threaded and defined within the imageable fiducial locator head . . . and a bone screw shaft that extends directly outward from the imageable fiducial locator head." As discussed above, Applicants respectfully submit that Leibinger and Vilsmeier, either alone or in combination, do not anticipate or fairly render obvious a fiducial marker that has a head, receptacle, and shaft, as recited in Independent Claim 23. In addition, as also discussed above, Applicants respectfully submit that Franklin also does not disclose a fiducial marker as recited in Independent Claim 23. Gordon is cited for a cover, and does not disclose a fiducial marker of any type. As noted above, Applicants submit that no proper reason for combining Leibinger and Vilsmeier has been provided. Accordingly, Applicants respectfully submit that Independent Claim 23 is not fairly

rendered obvious by any or all of Leibinger, Vilsmeier, Franklin, or Gordon.

In addition, Independent Claim 23 has been amended to recite "a protective cap sized and shaped for protecting the fiducial marker, wherein the protective cap has a disk-like portion with a threaded portion extending from the disk-like portion that is threadable into the receptacle and a cylindrical circumferential skirt extending from the disk-like portion in the same direction as the threaded portion." The Office cites Leibinger and Gordon for disclosing a protective cap. See, the Office Action, pg. 4 and 13. Leibinger, however, appears to simply disclose a cap 40 that can be positioned in the head 24 to cover a cavity. Leibinger clearly does not disclose a protective cap for protecting a fiducial marker, as claimed in Independent Claim 23, nor does it include a disk-like portion or a circumferential skirt as recited in Independent Claim 23.

Applicants submit that Gordon is directed to a cover for an implant rod that has a sharp tip. A cover, however, as disclosed in Gordon is not disclosed to be used in conjunction with any other system for covering a member other than an unsmooth wire. Accordingly, Applicants submit that the art provides no reason to combine the references as suggested the Office, and the Office provides no clear reason for the combination, which is required as discussed above.

Gordon also fails to disclose a cover as claimed. Gordon discloses a cover for orthopedic implants to protect the anatomy from a jagged portion, such as a burr formed on an edge of the implant. See Gordon, Abstract. The cover of Gordon includes a soft metal, either alone or encased within a plastic cover, as illustrated in Figs. 1 and 12, respectively, but fails to disclose a fiducial marker as recited in Independent Claim 23. In addition, Gordon does not disclose a disk-like portion or a circumferential skirt as recited in

Independent Claim 23. Further, Gordon discloses that the cover does not include a threaded portion extending from a disc-like portion that is threadable into a receptacle, as recited in Independent Claim 23. According to Gordon, the cover is gouged by the implant to hold it in place.

Applicants respectfully submit that the amended Independent Claim 23 is within the scope of the previous election. Further, no new subject matter is added to Independent Claim 23 and support for the amendments can be found throughout the application as filed, including at least paragraph 112 and Fig. 24.

Accordingly, Independent Claims 23 and 24 are in condition for allowance.

Independent Claim 25

Independent Claim 25 stands rejected under the combination of Franklin, Vilsmeier, and Gordon.

Independent Claim 25 has been amended to recite, "an imageable fiducial locator head . . . a conical receptacle . . . defined within the imageable fiducial locator head; and a bone screw shaft that extends directly outward from the imageable fiducial locator head." As discussed above, neither Franklin nor Vilsmeier disclose or fairly render obvious an imageable fiducial locator head that defines a receptacle therein or a bone screw shaft that extends directly therefrom.

Independent Claim 25 has been further amended to recite, "a protective cap sized and shaped for protecting the fiducial marker; wherein the protective cap has a proximal disk portion, a cylindrical circumferential portion extending from the proximal disk portion, and a distal base flange extending from the cylindrical circumferential

portion; wherein the cylindrical circumferential portion extends a distance from the proximal disk portion great enough such that the proximal disk portion extends over the imageable fiducial locator head and the distal ring flange; an adhesive portion positioned at the distal base flange for adhering the distal base flange to a scalp." Support for these amendments can be found in the application as filed, including at Fig. 26 and paragraph 114.

The Office only cites Gordon for a protective cap, and Applicants submit that neither Franklin nor Vilsmeier disclose any portion reasonably understood to be a protective cap as claimed. See, Office Action, p. 13. As discussed above, however, the cover of Gordon is either a sleeve of malleable metal alone or a sleeve within a plastic cap. The cover of Gordon is malleable such that it will selectively engage a burr. The cover of Gordon, however, does not disclose a distal base flange or an adhesive portion positioned at the distal base flange for adhering the distal base flange to a scalp. Further, Gordon discloses a malleable metal for engaging the burr of the metal implant and is held in place with the deformation caused by the burr and no other fixation is necessary or disclosed.

Accordingly, Independent Claim 25 is in condition for allowance.

Independent Claim 26

Independent Claim 26, and the claims that depend therefrom, stands rejected under the combination of Franklin, Vilsmeier, and Gordon.

Independent Claim 26 is amended to recite, "an imageable fiducial locator head that is locatable by an imaging system . . . a conical receptacle . . . defined within the

imageable fiducial locator head and configured to permit access to a center of the imageable fiducial locator head; and a bone screw shaft that extends directly outward from the imageable fiducial locator head.” As discussed above, none of these references disclosed or fairly render obvious a fiducial locator head that defines a receptacle and from which a shaft directly extends. Vilsmeier discloses two prominences and one fastener. Franklin discloses a scanning marker first positioned in a bone anchor, and later a fixture that is affixed to the bone anchor. Thus, neither of these references discloses a locator head as claimed. In addition, Gordon is directed only to a cover for a rod implant and not a fiducial marker at all.

In addition, Claims that depend from Independent Claim 26 also include patentable subject matter. Claim 27 recites, “the protective cap comprises: a disk-like base, including a center orifice; and a circumferential peripheral cylindrical sidewall extending away from the disk-like base and substantially open at a proximal end of the circumferential peripheral cylindrical sidewall away from the disk-like base.” Gordon only discloses a closed sleeve portion.

Claim 28 recites, “at least one radial slot in the disk-like base extending from the orifice.” Gordon discloses only an opening to accept a rod end and no disk-like base or a slot of any type in a base.

Claim 30 recites, “a disk-like cap sized and shaped to fit over a proximal portion of the sidewall.” Gordon discloses only a single piece sleeve and no disk-like cap as claimed.

Accordingly, Independent Claim 26 and the claims that depend therefrom are in condition for allowance.

Independent Claim 32

Claims 32 and 33 stand rejected under a combination of Leibinger, Vilsmeier, and Allen.

Initially, Applicants maintain that the combination of Allen with either Leibinger or Vilsmeier is improper. Applicants submit that Allen is not combinable with either Vilsmeier or Leibinger at least because Allen discloses an implant that is positioned within the patient and defines an internal coordinate system. The fiducial can be found with an instrument such as a sensor at the tip of a robot arm. The robot arm can identify or be positioned in an external coordinate system. See, Allen, col. 14, lns. 28-53. Contrary to Allen, Vilsmeier discloses that a first and second **separate** prominence members are positioned separately within a single fastener. The fastener is connected to an external portion of the patient with an adhesive. In Vilsmeier the two prominences are required because only one is imaged and the other is for position determination. Similarly, Leibinger discloses a marker 18 that can be positioned within a fixture 10. The marker 18 extends from the fixture and is removable from the fixture as illustrated in the various embodiments. Accordingly, while Allen requires that the fiducial be implanted into the patient and maintained for a correlation between internal and external coordinates, Vilsmeier and Leibinger disclose a marker or prominence that is imaged. At least for these reasons, Applicants submit that the reason to combine these references is also improper and, at most, is based on improper hindsight reasoning.

Claim 33 has also been amended to recite, "wherein the bone screw shaft includes a drivable portion that extends to the conical divot to be engaged with a driving

member.” Applicants respectfully submit that only Allen discloses a shaft, though Allen, either alone or in combination does not disclose or fairly render obvious all of the elements of Independent Claim 32. In addition, Allen discloses a polygonal opening in a top portion and not a drivable portion of a screw shaft that is engageable through a conical divot, as claimed in Claim 33.

Claim 58 is rejected under the combination of Leibinger, Vilsmeier, and Allen as applied to Independent Claim 32 and further in light of Frank. As discussed above, Frank does not disclose a head band defining an opening as recited in Independent Claim 58. Rather, Frank discloses that a fiducial 1412 is actually interconnected with an exterior of an art MIRRF 1410. Accordingly, Frank does not overcome the failing of Leibinger, Vilsmeier, and Allen to anticipate or fairly render obvious all of the elements of Independent Claim 58.

Accordingly, Independent Claims 32 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 36

Independent Claim 36 stands rejected under a combination of Allen, Vilsmeier, Kraus, and Stednitz or Ferrante.

Independent Claim 36 has been amended to recite, “a substantially spherical imageable locator head . . . including at least one slot extending through a side wall of the imageable locator head to be engaged by a driving instrument for driving in the fiducial marker to secure it to a bone; a conical receptacle defined within the imageable fiducial locator head by a substantially straight wall sloping to an apex at a center of the imageable fiducial locator head to permit access to the center of the imageable fiducial

locator head and wherein the slot intersects the conical receptacle; and a bone screw that extends directly outward from the imageable fiducial locator head.” Support for the amendments to Independent Claim 36 can be found throughout the Application as filed, including at least Claims 11 and 12 and Paragraphs 92-96. Further, amended Independent Claim 36 remains within the scope of the previous election.

Applicant’s respectfully submit that none of the cited references disclose an imageable fiducial locator head that defines a conical receptacle or slot as recited in Independent Claim 36. Allen discloses an allen wrench polygonal recess and teaches away from a Phillips driver or single groove receptor site. See, Allen, col. 7 Lines 55-61. Vilsmeier discloses a fastener that is adhered to a patient and prominence that includes a key or finger connection. Kraus is not directed to a fiducial marker and also discloses an allen wrench recess. Accordingly, Applicant’s respectfully submit that the amendments to Independent Claim 36 overcome the rejection based on these references.

Ferrante and Stednitz are cited for teaching a quarter cylindrical cutout. Ferrante and Stednitz, however, either alone or in combination with the other cited references, fail to disclose or fairly render obvious the imageable fiducial locator head, conical receptacle, and slot as recited in Independent Claim 36. Accordingly, these references do not overcome the failures of Allen, Vilsmeier, and Kraus to fairly render obvious all of the elements of Independent Claim 36.

Accordingly, Independent Claim 36 is in condition for allowance.

Independent Claim 49

Independent Claim 49 stands rejected under the combinations of (1) Leibinger and Vilsmeier and (2) Allen, Vilsmeier, Kraus, and either of Grafton or Leclair.

Independent Claim 49 has been amended to recite, “a substantially spherical imageable fiducial locator head . . . a conical receptacle . . . defined within the imageable fiducial locator head to permit access to a center of the imageable fiducial locator head; and a bone screw shaft that extends directly outward from the imageable fiducial locator.” As discussed above, Applicant’s respectfully submit that neither Leibinger nor Vilsmeier, either alone or in combination, anticipate or fairly render obvious a fiducial marker as recited in Independent Claim 49. Briefly, both Leibinger and Vilsmeier disclose or require at least two members for an imageable fiducial locator and a receptacle and not a locator head that also has a conical receptacle defined therein. Therefore, Leibinger and Vilsmeier, either alone or a combination, cannot anticipate or fairly render obvious all of the elements of Independent Claim 49.

As discussed above, Applicants respectfully submit that Allen, Vilsmeier, and Kraus cannot be properly combined. In addition, as discussed in relation to Independent Claim 36, Applicant’s respectfully submit that none of the references anticipate or fairly render obvious “at least one slot extending through a side wall of the imageable fiducial locator head to be engaged by a driving instrument for driving the fiducial marker to secure it to a bone.” Grafton and Leclair fail to overcome any of the failings of Allen, Vilsmeier, or Kraus regarding Independent Claim 49.

In addition, Grafton and Leclair are directed to fixation members and do not disclose the expandable distal tip, as claimed. Leclair only discloses a furcated bone screw and does not disclose “a member extending through at least a portion of the shaft

to engage the expandable distal tip and a passage through at least a portion of the imageable fiducial locator head to allow access to the member to manipulate the member to expand the expandable distal tip; wherein the passage defines internal threads and the member defines external threads, where the internal and external threads cooperate to move the member axially when the member is rotated." Grafton is also directed to a tissue anchor and does not disclose a fiducial marker as recited in Independent Claim 49. Thus, Grafton can not disclose "a passage through at least a portion of the imageable fiducial locator head to allow access to the member."

Accordingly, Independent Claim 49 is in condition for allowance.

Independent Claim 52

Independent Claim 52 stands rejected under a combination of Allen, Vilsmeier, Kraus, and Gordon.

Independent Claim 52 has been amended to recite, "a substantially spherical imageable fiducial locator head . . . including at least one slot extending through side wall of the imageable fiducial locator head to be engaged by a driving instrument for driving the fiducial marker to secure it to a bone." As discussed above, Applicants respectfully submit that Allen, Vilsmeier, and Kraus do not anticipate or fairly render obvious a fiducial locator head as recited in Independent Claim 52.

Gordon is directed to a sleeve formed of malleable metal to be gouged by a burr of a metal rod implant. As discussed above, Gordon is not directed to a fiducial marker, as recited in Independent Claim 52. In addition, Independent Claim 52 has been amended to recite, "wherein the protective cap has a proximal disk portion, a cylindrical

circumferential portion extending from the proximal disk portion, and a distal base flange portion extending from the cylindrical circumferential portion . . . an adhesive portion positioned at the distal base flange for adhering the distal base flange to a scalp. Applicants respectfully submit that even if the sleeve of Gordon could be interpreted to be a protective cap, as recited in Independent Claim 52, Gordon does not disclose the distal base flange or adhesive portion as recited in Independent Claim 52.

Accordingly, Independent Claim 52 is in condition for allowance.

Independent Claim 53

Independent Claim 53 stands rejected under a combination of Allen, Vilsmeier, Kraus, and Gordon.

Independent Claim 53 has been amended to recite, “a substantially spherical imageable fiducial locator head . . . including at least one slot extending through a side wall of the imageable fiducial locator head to be engaged by a driving instrument for driving the fiducial marker to secure it to a bone; a conical receptacle . . . defined within the imageable fiducial locator head to permit access to a center of the imageable fiducial locator head; a bone screw shaft that extends directly outward from the imageable fiducial locator head . . . and a protective cap sized and shaped for protecting the fiducial marker.”

As discussed above, Applicants respectfully submit that the combination of Allen, Vilsmeier, Kraus, and Gordon does not anticipate or fairly render obvious all of the elements of Independent Claim 53. Independent Claim 53, for example, includes a fiducial locator head having a slot extending through its sidewall. Applicants respectfully

submit that none of the references cited in the rejection disclose a slot extending through a sidewall of an imageable fiducial locator head. In addition, together the protective cap recited in Independent Claim 53 and the fiducial marker are not anticipated or fairly rendered obvious by the art cited in the rejection. As discussed above, Gordon is directed only to a malleable metal sleeve that can be gauged by a burn on a metal rod.

In addition, claims that depend from an Independent Claim 53 also include patentable subject matter. For example, Claim 54 recites, "the protective cap comprises: a disk-like base defining a first diameter and a center orifice having a second diameter less than the first diameter; and a circumferential peripheral cylindrical sidewall defining a third diameter greater than the second diameter." Even assuming that Gordon discloses a protective cap, Gordon discloses a sleeve that has an open base that does not include an orifice of a diameter as recited in Claim 54.

Claim 55 recites, a "radial slot in the base." Because Gordon does not disclose a base, Gordon cannot disclose a radial slot in a base, as recited in Independent Claim 55.

Accordingly, Independent Claim 53 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 59

Independent Claim 59 stands rejected under the combinations of (1) Leibinger and Vilsmeier and (2) Allen and Vilsmeier.

Independent Claim 59 is directed to a method for “driving directly into a bone of a patient a fiducial marker device including both at least a semispherical imageable locator fiducial head and an integral conical receptacle defined by the imageable fiducial locator head . . . providing a substantially straight wall from an edge defined by a surface of the imageable fiducial locator head to the apex of the conical receptacle...”

As discussed above, Applicants respectfully submit that neither of Vilsmeier nor Leibinger disclose or fairly render obvious a fiducial marker that has **both** an imageable fiducial locator head and a conical receptacle defined by the imageable fiducial locator head. Vilsmeier discloses only a fastener with two prominences that can be separately and individually interconnected with the fastener and Leibinger discloses a marker 18, interconnected with a fixture 10. Accordingly, neither discloses a fiducial marker that includes the two claimed portions that can be driven directly into a bone. Allen discloses a fiducial marker that is implanted in a patient, but also fails to disclose an imageable fiducial locator head that defines a conical receptacle and providing a substantially straight wall as recited in Independent Claim 59.

Because the art does not disclose a fiducial marker with the portions recited it can not disclose an instrument interacting with them. Thus, the cited art can not disclose a method of accessing the apex with an instrument by moving the instrument towards the apex and mating the instrument to the receptacle as recited in Independent Claim 59.

Accordingly, Independent Claim 59 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 64

Independent Claim 64 stands rejected under three combinations: (1) Leibinger and Vilsmeier; (2) Franklin, Vilsmeier, and one of Stednitz or Ferrante and one of Grafton or Leclair; and (3) Allen, Vilsmeier, Krauss and one of Grafton or Leclair.

Independent Claim 64 is directed to a method of driving directly into bone a fiducial marker, including both of and "imageable fiducial locator head and an integral conical receptacle defined within the imageable fiducial locator head." As discussed above, Applicants respectfully submit that Leibinger and Vilsmeier, either alone or in combination, fail to anticipate or fairly render obvious a fiducial marker that has both a fiducial locator head and a conical receptacle as recited in the method of Independent Claim 64. In addition, Independent Claim 64 has been amended to recite "engaging a member positioned within a distal portion of the fiducial marker through the conical receptacle; and rotating the member to axially move the member and laterally expand the distal portion." Applicants respectfully submit Leibinger and Vilsmeier, either alone or in combination, fail to anticipate or fairly render obvious engaging a member and laterally expanding the distal portion as recited in Independent Claim 64. As discussed above, Vilsmeier discloses that two prominences can be interconnected with a fastener and the fastener is adhered to a patient and Leibinger discloses that a marker 18 can be interconnected in a fixture 10. Neither discloses, however, expanding a distal portion with a member.

Applicants respectfully submit that none of Franklin, Vilsmeier, Stednitz, Ferrante, Grafton or Leclair discloses driving a fiducial marker, including both of the fiducial locator head and a conical receptacle as recited in Independent Claim 64. Vilsmeier is discussed immediately above, and Franklin is directed to positioning a scanning marker 120 within a bone anchor. Accordingly, Franklin does not disclose driving a fiducial marker including a

fiducial locator head and a conical receptacle directly into a patient, as recited in Independent Claim 64. Stednitz and Ferrante are cited for threadable portions, and are not directed to driving a fiducial marker into bone, as recited in Independent Claim 64. Leclair is directed to a furcated bone screw, but does not disclose driving a fiducial marker into a patient, or engaging a member positioned within a distal portion of the fiducial marker through a conical receptacle. Finally, Grafton is also directed to a fastener, and does not disclose an imageable fiducial locator head. Accordingly, Grafton also fails to overcome the failings of the other cited art to render obvious engaging a member through a conical receptacle.

The combination of Allen, Vilsmeier, and Kraus is previously discussed as being improper, and even if proper does not render obvious all of the elements of Independent Claim 64. Initially, Allen discloses mating a fiducial marker directly with a patient while Vilsmeier is directed to two prominences which are separately and individually connected with a fastener. Kraus is not directed to a fiducial marker at all, and discloses a screw. Kraus also fails to disclose providing a substantially flat wall from an edge defined by a surface of the imageable fiducial locator head to an apex of a conical receptacle. As clearly illustrated in Kraus, an allen wrench or polygonal receptacle is provided with only small dip (not numbered). Grafton and Leclair do not overcome the failings of Allen, Vilsmeier, and Kraus with regard to the driving of the fiducial marker or providing the straight wall. In addition, as discussed above, Grafton and Leclair fail to anticipate or fairly render obvious rotating the member to axially move the member and laterally expand a distal portion.

Accordingly, Independent Claim 64 is in condition for allowance.

Independent Claim 65

Independent Claim 65 stands rejected under a combination of Franklin, Vilsmeier and Gordon.

Independent Claim 65 has been amended to recite a method of driving directly into a bone “a fiducial marker device including both and at least a semispherical imageable fiducial locator head and an integral conical receptacle defined by the imageable fiducial locator head.” Because Franklin and Vilsmeier do not disclose a fiducial marker having both an imageable fiducial locator head and an integral conical receptacle, as discussed above, they, either alone or in combination, cannot anticipate or fairly render obvious a method of driving such a fiducial marker into a bone. In addition, Applicants submit that there is no real reason to combine Franklin and Vilsmeier. Though the Office notes that one skilled may wish to increase precision, Applicants submit that the combined art does not disclose how increased precision would be achieved or how the increased precision would render obvious the present claims.

Gordon, also as discussed above, is not directed to a fiducial marker. Accordingly, Gordon can not overcome the failings of Franklin and Vilsmeier. In addition, Independent Claim 65 has been amended to recite “disposing a protective collar into association with the fiducial marker device by passing a shaft extending from the imageable fiducial locator head through a peripheral slot and a radial slot in a base of the protective collar.” As discussed above, Gordon discloses a sleeve that can be gouged by a burr on a metal implant. Gordon does not disclose a base of a protective collar, or a base with both a peripheral slot and a radial slot in the base. Gordon only

discloses an opening that is passed over a portion of the implant and sides that are gouged by the implant.

Accordingly, Independent Claim 65 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 68

Independent Claim 68 stands rejected under the combination of Leibinger, Vilsmeier, Allen and Winters (U.S. Patent No. 6, 464,706).

As noted by the Office, none of Leibinger, Vilsmeier or Allen disclose a guide collar as recited in Independent Claim 68. Applicants submit that none of these references disclose a fiducial marker that also includes both at least a semispherical imageable locator head and an integral conical receptacle. As discussed above, each of these references fail to disclose or fairly render obvious, alone or in combination, a fiducial marker including both of these elements.

Only Winters is cited for disclosing disposing a guide collar as recited in Independent Claim 68. Independent Claim 68, however, has been amended to recite "disposing a guide collar assembly about the fiducial marker device before the driving, wherein disposing the guide collar assembly includes providing a first member and disposing a second member at least partially around the first member; removing the second member of the guide collar assembly after the driving; and leaving only the first member of the guide collar about the fiducial marker during a time period." Winters appears to only disclose a cannula 62 and a cannula bore 620. Winters discloses that a cannula is removed from a surgical site and a barb 663 is permitted to bear against soft

tissue. See, Winters, Col. 6, Lines 47-49. Accordingly, Winters does not disclose and actually teaches away from disposing a guide collar assembly, including a first and second member, and removing a second member while leaving only a first member of the guide collar assembly in place. Moreover, Winters is directed to tissue fixation and is not directed to or does it disclose a fiducial marker as recited in Independent Claim 68. Accordingly, Winters does not overcome the failings of the other cited art to anticipate or fairly render obvious all of the elements of Independent Claim 68, and even fails to disclose a method of a guide collar assembly including removing a second member and leaving only a first member, as recited in Independent Claim 68.

Accordingly, Independent Claim 68 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 76

Independent Claim 76 stands rejected under two combinations, (1) Franklin, Vilsmeier, and Gordon and (2) Allen, Vilsmeier, Kraus, and Gordon.

Independent Claim 76 has been amended to recite, “an imageable fiducial locator head that is locatable by an imaging system; . . . the receptacle integrated with the imageable fiducial locator head; and a bone screw shaft extends directly outward from the imageable fiducial locator head . . . ; and a protective cap sized and shaped for protecting the fiducial marker; wherein the protective cap includes an inner member defining an external thread and outer member defining an internal thread, wherein the outer member can be rotated relative to the inner member to adjust a height of the outer member relative to the inner member.” Initially, as discussed above, Applicants submit

that none of the cited art, either alone or in combination, anticipate or fairly render obvious a fiducial marker with both the imageable fiducial locator head and receptacle as claimed. Further, only Gordon is cited for teaching a protective cap. See, Office Action, p. 13 and 22. Gordon, however, does not disclose or fairly render obvious an inner and outer member with a threaded engagement there between, as claimed. Gordon discloses either a single piece metal sleeve or a metal sleeve within a plastic cap where the metal sleeve can be gouged when engaging a clipped implant. Neither embodiment illustrated in Gordon discloses an inner and outer member that are threadably connected or can move relative to each other. The other cited art do not overcome the failings of Gordon in this respect of teaching a protective cap.

Also, Claims that depend from Independent Claim 76 include patentable subject matter. Claim 77 recites, "the protective cap comprises: a disk-like portion including a threaded member extending from the disk-like portion to engage a thread in the conical receptacle to connect the inner member and the imageable fiducial locator head." As discussed above, Gordon teaches a sleeve that engages a rod and is gouged by the rod. Gordon does not disclose a threaded member extending from a disk-like portion as claimed. Again, the other cited art do not overcome the failings of Gordon in this respect of teaching a protective cap.

Accordingly, Independent Claim 76 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 81

Independent Claim 81 is rejected under three combinations, (1) Leibinger and Vilsmeier; (2) Franklin, Vilsmeier, one of Stednitz or Ferrante, and one of Grafton or Leclair; and (3) Allen, Vilsmeier, Kraus, and one of Grafton or Leclair. Independent Claim 81, however, has been amended to include the elements of Claim 87, which has now been canceled. Claim 87 is only rejected under the combinations of (1) Leibinger and Vilsmeier and (3) Allen, Vilsmeier, Kraus, and one of Grafton or Leclair.

Independent Claim 81 has been further amended to recite, “an imageable fiducial locator head . . . a male or female receptacle defined by the imageable fiducial locator head.” As discussed above, Leibinger and Vilsmeier, alone or in combination, fail to anticipate or fairly render obvious a fiducial marker including a head that both is imageable and defines a receptacle, as recited in Independent Claim 81. Both disclose, at most, separate members that must be used separately to image and have a locatable portion. As also discussed above, Allen, Kraus, and Vilsmeier do not disclose a fiducial marker including a head that is imageable and that defines a receptacle, as recited in Independent Claim 81.

Independent Claim 81 has been further amended to recite, “an imageable plug, sized and shaped to fit within the receptacle and locatable with the imaging system.” While the Office submits that Leibinger has a “plug,” Leibinger only discloses a cap 40 that can be removed to allow access to a cavity to place a contrasty substance in the cavity. See, Office Action, p. 4; Leibinger, col. 4, ln. 67 to col. 5, ln. 10. Leibinger, however, does not disclose that the cap 40 is imageable, but only that it allows access to a cavity to hold the contrasty agent. Kraus is also cited for disclosing a plug. See,

office Action, p. 19. Kraus, however, discloses a locking element to hold a wire in place. Kraus is not directed to a fiducial marker. Kraus also fails to disclose that the locking member is an imageable plug. The other cited art also fail to disclose an imageable plug, as claimed.

Accordingly, Independent Claim 81 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 88

Independent Claim 88 stands rejected under the combination of Allen, Vilsmeier, Kraus, and one of Stednitz and Ferrante.

Independent Claim 88 has been amended to recited, “a substantially spherical imageable fiducial locator head . . . a receptacle . . . defined within the imageable fiducial locator head . . . a bone screw shaft that connects to and extends directly outward from the imageable fiducial locator head.” Applicants respectfully submit that Allen, Vilsmeier, and Kraus, either alone or in combination, do not anticipate or fairly render obvious a fiducial marker that has both an imageable fiducial locator head and that the head defines a receptacle, as recited in Independent Claim 88. As discussed above, Vilsmeier discloses that at least two prominences are required to be separately connected with a fastener and does not disclose a bone shaft that connects to and extends from an imageable fiducial locator head. Allen also fails to disclose a locator head defining a receptacle therein. While Krause is directed to a locking element for a device for promoting formation of bone, Kraus does not disclose a fiducial marker. Applicants respectfully submit that Stednitz and Ferrante are both directed only to a

fastener system, and also do not disclose a fiducial marker as claimed in Independent Claim 88.

In addition, Independent Claim 88 has been amended to recite, "an imageable plug, sized and shaped to fit within the receptacle defined within the imageable fiducial locator head, wherein the imageable plug includes a fin operable to cooperate with the slot such that the imageable fiducial locator head and the imageable plug together presents a uniformly shaped imageable portion to the imaging system." Applicants respectfully submit that the subject matter added to Independent Claim 88 is supported by the application as filed including at least Claim 89, Figures 14 and 15 and the associated description text.

Applicants respectfully submit that none of the references either alone or in combination, anticipate or fairly render obvious an imageable plug as recited in Independent Claim 88. As discussed above, Kraus discloses a locking element for holding a wire relative to a bone screw 12 for bone formation. Kraus does not disclose an imageable plug that fits within a receptacle to present the uniformly shaped imageable portion to an imaging system. Also, as discussed above, Vilsmeier discloses a cap for closing a cavity, but does not disclose an imageable plug. The cavity holds a contrasty agent, but the cap is not disclosed to be imageable.

Accordingly, Independent Claim 88 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 91

Independent Claim 91 stands rejected under the combination of (1) Leibinger and Vilsmeier and (2) Allen, Vilsmeier, Krause, and McCrory et al. (U.S. Patent No. 6,333,971 (herein McCrory)).

As discussed above, Applicants respectfully submit that the combination of Leibinger and Vilsmeier do not disclose a unitary fiducial marker including an imageable fiducial locator head and a receptacle integrated with the imageable fiducial locator head to permit access to the center of the imageable fiducial locator head. In addition, Independent Claim 91 recites, "a bone screw shaft that extends outward from the imageable fiducial locator . . . [and] integrated with the imageable fiducial locator head." As discussed above, neither Leibinger nor Vilsmeier disclose a single imageable fiducial locator head that also includes a receptacle and shaft.

Independent Claim 91 also recites, "an imageable plug, sized and shaped to fit within the receptacle." As also discussed above, although Leibinger discloses a cap 40 to close a cavity, Leibinger does not disclose a receptacle to permit access to a center of the imageable fiducial head or an imageable plug that is shaped to fit within the receptacle. Leibinger only discloses a cap to maintain a contrasty agent within a cavity. Applicants respectfully submit that neither Allen nor Krause overcome this failing of Vilsmeier. McCrory discloses that a cap 16 can seal a cylinder 12 that contains a mixture of imaging agents. *See*, McCrory, col. 5; Ins. 34-37. The cylinder 12, however, is not integrated with a bone shaft as it is removably connected to a base 30. Thus, McCrory also fails to overcome the failings of the other cited art and McCrory does not

disclose or fairly render obvious a bone screw shaft that is integrated with an imageable fiducial locator head or an imageable plug.

In addition, the claims that depend from Independent Claim 91 also include patentable subject matter. For example, dependent Claim 93 recites, “a groove operable to collect a material as the screw shaft is connected to a bone.” Applicants respectfully submit that none of the references disclose a groove operable to collect material as recited in dependent Claim 93. The Office notes that Leibinger in Figure 13 discloses a kerf, but Applicants submit that there is no description of a kerf in Leibinger or an illustrated physical structure of a kerf or a groove operable to collect a material.

Accordingly, Independent Claim 91 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 94

Independent Claim 94 stands rejected under the combination of Allen, Vilsmeier, Krause, and one of Grafton or Leclair.

Independent Claim 94 has been amended to be directed to a method of driving directly into a bone a fiducial marker including “both an imageable fiducial locator head and an integral male or female receptacle.” As previously argued, Applicants respectfully submit that none of Allen, Vilsmeier, or Krause disclose a fiducial marker having both a locator head and an integral receptacle, as recited in Independent Claim 94. Accordingly, these references can not disclose a method of driving such a device directly into a bone of a patient. Additionally, as discussed above, neither Grafton nor Leclair are directed to a fiducial marker or a method of driving a fiducial marker.

Accordingly, these references do not overcome the failings of Allen, Vilsmeier, and Krause.

Independent Claim 94 has been further amended to recite, “rotating a member to axially move the member to laterally expand a distal portion of the device.” As discussed above, Leclair is directed to a furcated bone screw and does not disclose a member to laterally expand any portion. Grafton is directed to an expandable tissue anchor that uses a cannulated pin insertion assembly 28 and a pin driver 30 to expand an anchor. Grafton does not disclose rotating a member to axially move the member as recited in Independent Claim 94. Accordingly, even assuming that the other cited art discloses driving directly into a bone or fiducial marker, as recited in Independent Claim 94, a member to laterally expand a distal portion is not disclosed in either Grafton or Leclair.

Accordingly, Independent Claim 94 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 98

Independent Claim 98 stands rejected under the combination of Leibinger, Vilsmeier, Allen and Winters.

As noted by the Office, none of Leibinger, Vilsmeier, or Allen discloses disposing a guide collar or a guide collar assembly. See, the Office Action, pg. 5. While Winters is cited to disclose a guide collar, Winters is directed to a tissue fixation device where a screw 64 is inserted through a cannula and barbs of a washer are permitted to bear against soft tissue when the cannula is removed. See, Winters, col. 6, Ins. 40-50.

Winters does not disclose the method recited in Independent Claim 98. Independent Claim 98 has been amended to recite, "disposing a guide collar assembly, having a first member and a second member disposed around the first member, about a fiducial marker device. . . driving directly into a bone . . . the fiducial marker device. . . through the guide collar assembly; removing only the second member of the guide collar assembly axially from the fiducial marker; leaving the first member of the guide collar assembly about the fiducial marker during a time period after removing the second member in which the patient is to be protected against a mechanical impact to the fiducial marker." Applicants respectfully submit that Winters is not directed to a fiducial marker. Moreover, Winters does not disclose a guide collar assembly including a first and second member where only a second member is removed and a first member is maintained around a fiducial marker. Winters discloses removing a cannula to allow barbs to engage soft tissue.

Accordingly, Independent Claim 98 and all of the claims that depend therefrom are in condition for allowance.

Independent Claim 101

Independent Claim 101 stands rejected under the combination of Leibinger, Vilsmeier, Allen, and Winters.

The Office notes that none of Leibinger, Vilsmeier, and Allen discloses a guide collar or guide collar assembly or a method including a guide collar assembly. See, Office Action, pg. 5. Although Winters discloses a cannula, as discussed above, Winters discloses removing the cannula to allow a barb to engage soft tissue.

Independent Claim 101, to the contrary, discloses a method of disposing a guide collar assembly about a fiducial marker device "wherein the guide collar assembly includes a first inner member and a second outer member positioned around the first inner member; driving directly into a bone . . . the fiducial marker device . . . through the guide collar assembly; leaving the first inner member of the guide collar assembly about the fiducial marker device during a time period in which the patient is to be protected against a mechanical impact to the fiducial marker after the driving; removing the first inner member of the guide collar assembly laterally from the fiducial marker." As discussed above, Applicants respectfully submit that Winters discloses removing a cannula and does not disclose a guide collar assembly. In addition, Winters does not disclose removing a cannula laterally, much less the first member of a collar assembly laterally.

Accordingly, Independent Claim 101 and all of the claims that depend therefrom are in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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